

**TRANSLATION**      **PATENT COOPERATION TREATY**  
**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>DRP 027 - PCT</b>	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. <b>PCT/IB2004/003151</b>	International filing date (day/month/year) <b>28.09.2004</b>	Priority date (day/month/year) <b>01.10.2003</b>
International Patent Classification (IPC) or national classification and IPC <b>B01 F7/00, B01 F5/04, B01 F3/08, B01 F15/02, B01J13/02, A61 K9/16</b>		
Applicant <b>DEBIO RECHERCHE PHARMACEUTIQUE S.A.</b>		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>4</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;"><input checked="" type="checkbox"/></td> <td style="width: 15%;"><b>Box No. I</b></td> <td style="width: 70%;"><b>Basis of the report</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. II</b></td> <td><b>Priority</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. III</b></td> <td><b>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. IV</b></td> <td><b>Lack of unity of invention</b></td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><b>Box No. V</b></td> <td><b>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><b>Box No. VI</b></td> <td><b>Certain documents cited</b></td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><b>Box No. VII</b></td> <td><b>Certain defects in the international application</b></td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><b>Box No. VIII</b></td> <td><b>Certain observations on the international application</b></td> </tr> </table>	<input checked="" type="checkbox"/>	<b>Box No. I</b>	<b>Basis of the report</b>	<input type="checkbox"/>	<b>Box No. II</b>	<b>Priority</b>	<input type="checkbox"/>	<b>Box No. III</b>	<b>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</b>	<input type="checkbox"/>	<b>Box No. IV</b>	<b>Lack of unity of invention</b>	<input checked="" type="checkbox"/>	<b>Box No. V</b>	<b>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</b>	<input type="checkbox"/>	<b>Box No. VI</b>	<b>Certain documents cited</b>	<input checked="" type="checkbox"/>	<b>Box No. VII</b>	<b>Certain defects in the international application</b>	<input checked="" type="checkbox"/>	<b>Box No. VIII</b>	<b>Certain observations on the international application</b>
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Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IB2004/003151

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

international search (Rule 12.3 and 23.1(b))  
 publication of the international application (Rule 12.4)  
 international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished  
 the description:  
 pages 1-52 as originally filed/furnished  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:  
 nos. \_\_\_\_\_ as originally filed/furnished  
 nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19  
 nos.\* 1-12 received by this Authority on 05.10.2005 with letter  
of 27.06.2005  
 nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:  
 sheets 1/8-8/8 as originally filed/furnished  
 sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
 sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_  
 the claims, nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_  
 the claims, nos. \_\_\_\_\_  
 the drawings, sheets/figs \_\_\_\_\_  
 the sequence listing (*specify*): \_\_\_\_\_  
 any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/IB2004/003151

Box No. V      Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-12	YES
	Claims	-	NO
Inventive step (IS)	Claims	1-12	YES
	Claims	-	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims	-	NO

## 2. Citations and explanations (Rule 70.7)

## 1. Reference is made to the following documents:

D1: US-A-2 641 453 (TEALE ROBERT R) 9 June 1953  
(1953-06-09);

D2: US-A-4 416 548 (CARRE OLOF G ET AL)  
22 November 1983 (1983-11-22).

## 2.1 Document D2, which is considered to be the most relevant prior art, describes (cf. figure 1):

- *a device for continuously producing microparticles or nanoparticles from at least one aqueous phase and one organic phase, which device includes a cylinder-shaped homogenising compartment (1) defined by a tubular wall forming the casing of said cylinder and by a first and a second side wall at each end of said tubular wall, as well as a first and a second inlet (4, 6) extending through said first side wall and suitable for supplying an organic phase and an aqueous phase, respectively, to said homogenising compartment, and an outlet (5) for extracting a suspension*

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p><i>of particles from said homogenising compartment, wherein said homogenising compartment contains a mixing system including a rotor (2) / stator (8) assembly, and:</i></p> <p class="list-item-l1">(a) <i>said side walls are positioned in a vertical plane,</i></p> <p class="list-item-l1">(b) <i>the axis of symmetry of said cylinder is horizontal,</i></p> <p class="list-item-l1">(c) <i>the rotor is rotatably mounted about a horizontal axis extending through said second side wall,</i></p> <p class="list-item-l1">(d) <i>said first inlet (6) is a tube in alignment with the axis of said rotor (2), and</i></p> <p class="list-item-l1">(e) <i>said homogenising compartment has an upper edge on which said outlet is located.</i></p>

The subject matter of **claim 1** differs from the above in that *said tube includes an end portion that is located inside said rotor and inside said stator.*

It follows that the subject matter of **claim 1** is novel (PCT Article 33(2)).

The problem that the present invention is intended to solve can therefore be considered to be that of proposing an alternative design for said device.

The solution to this problem, as proposed in **claim 1** of the present application, is considered to

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

involve an inventive step (PCT Article 33(3)) because none of the cited documents describes or suggests those features in **claim 1** that differ from D2.

Even though document D1 describes a device that includes a tube of which the end portion is located inside the rotor and inside the stator, said device is positioned vertically, i.e. the axis of symmetry of the homogenising compartment is vertical and, as a result, the outlet of said compartment is arranged horizontally. According to the invention, such an arrangement has adverse effects. Arranging the outlet on the upper edge of the homogenising compartment prevents excess air from being input into the compartment and thereby prevents deformed particles from being produced (see page 6, lines 1-4).

- 2.2 As far as **claim 8** is concerned, a method that uses the device as per **claim 1** must be considered to be novel (PCT Article 33(2)) and to involve an inventive step (PCT Article 33(3)).
- 2.3 **Claim 12** can be considered to be novel (PCT Article 33(2)), to involve an inventive step (PCT Article 33(3)) and to fulfil the requirement of unity of invention, as set forth in PCT Rule 13.1 and 13.2, only when it clearly indicates the use of a device as per **claim 1**.
- 3.1 **Claims 2-7** are dependent on **claim 1** and, as such,

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therefore also fulfil the PCT requirements of novelty and inventive step.

3.2      **Claims 9-11** are dependent on **claim 8** and, as such, therefore also fulfil the PCT requirements of novelty and inventive step.

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**Box No. VII      Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

1.      Contrary to the requirements of PCT Rule 5.1(a)(ii), the description does not indicate the relevant prior art disclosed in documents D1 and D2, nor does it cite said documents.

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## Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Some of the features set out in **device claim 1** serve more to explain the way in which the device is used (in particular, the definition of the substances to be supplied via the various inlets and outlets to said device) than to define the device clearly in terms of technical features. It follows that the restrictions intended by these features are not clear from said claim, contrary to the requirement of PCT Article 6. As a result, these features cannot be taken into consideration in order to differentiate said claim from the documents cited in the search report.